

Application No.: 10/726,625

Docket No.: N9810.0033/P033

AMENDMENTS TO THE CLAIMS

1.-15. (Cancelled).

16. (Currently amended). The method composition of claim 56[[15]], wherein the spray composition further comprises ~~comprising~~ a flavoring agent in an amount between 0.05 and 10 percent by weight of the total composition.

17. (Currently amended). The method composition of claim 16, wherein the polar solvent is present in an amount between 20 and 97 percent by weight of the total composition, the active compound is present in an amount between 0.1 and 15 percent by weight of the total composition, the propellant is present in an amount between 2 and 5 percent by weight of the composition, and the flavoring agent is present in an amount between 0.1 and 5 percent by weight of the total composition.

18. (Currently amended). The method composition of claim 17, wherein the polar solvent is present in an amount between 25 and 97 percent by weight of the total composition, the active compound is present in an amount between 0.2 and 25 percent by weight of the total composition, the propellant is present in an amount between 2 and 4 percent by weight of the composition, and flavoring agent is present in an amount between 0.1 and 2.5 percent by weight of the total composition.

19. (Currently amended). The method composition of claim 56[[15]], wherein the polar solvent is selected from the group consisting of polyethyleneglycols having a molecular weight between 400 and 1000, C<sub>2</sub> to C<sub>8</sub> mono- and poly-alcohols, and C<sub>7</sub> to C<sub>18</sub> alcohols of linear or branched configuration.

20. (Currently amended). The method composition of claim 19, wherein the polar solvent comprises aqueous polyethylene glycol.

21. (Currently amended). The method composition of claim 19, wherein the polar solvent comprises aqueous ethanol.

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22. (Currently amended). The ~~method composition~~ of claim 56[[15]], wherein the active compound is an anti-opioid agent selected from the group consisting of naloxone, nalmeferene, naltrexone, cholecystokinin, nociceptin, neuropeptide FF, oxytocin, vasopressin, and mixtures thereof.

23. (Currently amended). The ~~method composition~~ of claim 56[[15]], wherein the active compound is an anti-migraine agent selected from the group consisting of frovatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan, naratriptan, almotriptan, ergotamine, diethylergotamine, sumatriptan, and mixtures thereof.

24. (Currently amended). The ~~method composition~~ of claim 56[[15]], wherein the active compound is a pain control agent selected from the group consisting of non-steroidal anti-inflammatory drugs, alfentanil, butorphanol, codeine, dezocine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, propoxyphene, pentazocine, sufentanil, tramadol, and mixtures thereof.

25. (Currently amended). The ~~method composition~~ of claim 56[[15]], wherein the active compound is an anesthetic selected from the group consisting of benzonatate, bupivacaine, desflurane, enflurane, isoflurane, levobupivacaine, lidocaine, mepivacaine, prilocaine, propofol, rapacuronium bromide, ropivacaine, sevoflurane, ketamine, and mixtures thereof.

26. (Currently amended). The ~~method composition~~ of claim 16, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

27. (Currently amended). The ~~method composition~~ of claim 56[[15]], wherein the propellant is selected from the group consisting of propane, *N*-butane, *iso*-butane, *N*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

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Claims 28 – 41 (Canceled).

42. (Currently amended). The method composition of claim 57[[41]], wherein the spray composition further comprises ~~comprising~~ a flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

43. (Currently amended). The method composition of claim 42, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

Claim 44 (Canceled).

45. (Currently amended). The method composition of claim 58[[44]], wherein the propellant is present in an amount between 20 and 70 percent by weight of the total composition, the non-polar solvent is present in an amount between 25 and 75 percent by weight of the total composition, the active compound is present in an amount from between 0.25 and 35 percent by weight of the total composition, and the flavoring agent is present in an amount between 2 and 7.5 percent by weight of the total composition.

46. (Currently amended). The method composition of claim 42, wherein the propellant is selected from the group consisting of propane, *n*-butane, *iso*-butane, pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

47. (Currently amended). The method composition of claim 46, wherein the propellant is *n*-butane or *iso*-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

48. (Currently amended). The method composition of claim 57[[41]], wherein the solvent is selected from the group consisting of (C<sub>2</sub>-C<sub>24</sub>) fatty acid (C<sub>2</sub>-C<sub>6</sub>)

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esters, C<sub>7</sub>-C<sub>18</sub> hydrocarbons of linear or branched configuration, C<sub>2</sub>-C<sub>6</sub> alkanoyl esters, and triglycerides of C<sub>2</sub>-C<sub>6</sub> carboxylic acids.

49. (Currently amended). The method composition of claim 48, wherein the solvent is miglyol.

50. (Currently amended). The method composition of claim 57[[41]], wherein the active compound is an anti-opioid agent selected from the group consisting of naloxone, nalmefene, naltrexone, cholecystokinin, nociceptin, neuropeptide FF, oxytocin, vasopressin, and mixtures thereof.

51. (Currently amended). The method composition of claim 57[[41]], wherein the active compound is an anti-migraine agent selected from the group consisting of frovatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan, naratriptan, almotriptan, ergotamine, diethylergotamine, sumatriptan, and mixtures thereof.

52. (Currently amended). The method composition of claim 57[[41]], wherein the active compound is a pain control agent selected from the group consisting of non-steroidal anti-inflammatory drugs, alfentanil, butorphanol, codeine, dezocine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, propoxyphene, pentazocine, sufentanil, tramadol, and mixtures thereof.

53. (Currently amended). The method composition of claim 57[[41]], wherein the active compound is an anesthetic selected from the group consisting of benzonatate, bupivacaine, desflurane, enflurane, isoflurane, levobupivacaine, lidocaine, mepivacaine, prilocaine, propofol, rapacuronium bromide, ropivacaine, sevoflurane, ketamine, and mixtures thereof.

Claims 54-55 (Canceled).

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56. (New) A method for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of the active compound through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a buccal spray composition, containing a pharmacologically active compound dissolved in a pharmacologically acceptable solvent, comprising in weight percent of the composition:

an active compound in an amount of between 0.1 and 25 percent selected from the group consisting of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof;

a polar solvent in an amount between 10 and 97 percent; and

a propellant in an amount between 2 and 10 percent, wherein said propellant is a C<sub>3</sub> to C<sub>8</sub> hydrocarbon of linear or branched configuration.

57. (New) A method for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of the active compound through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a buccal spray composition, containing a pharmacologically active compound dissolved in a pharmacologically acceptable solvent, comprising in weight percent of the composition:

an active compound in an amount between 0.05 and 50 percent selected from the group consisting of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof;

a non-polar solvent in an amount between 19 and 85 percent; and

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a propellant in an amount between 5 and 80 percent, wherein said propellant is a  $C_3$  to  $C_8$  hydrocarbon of linear or branched configuration.

58. (New) A method for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of the active compound through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a buccal spray composition, containing a pharmacologically active compound dissolved in a pharmacologically acceptable solvent, comprising in weight percent of the composition:

an active compound in an amount between 0.01 and 40 percent selected from the group consisting of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof;

a non-polar solvent in an amount between 25 and 89 percent;

a propellant in an amount between 10 and 70 percent, wherein said propellant is a  $C_3$  to  $C_8$  hydrocarbon of linear or branched configuration; and

a flavoring agent in an amount between 1 and 8 percent.